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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/049,587

02/12/2002

Douglas E. Brenneman

15280W-0021US

9701

7590

03/14/2006

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EXAMINER

STANDLEY, STEVEN H

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/049,587	BRENNEMAN ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12/07/06.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 7,10-41 and 54-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9 and 42-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 1-9, 42-53) and SEQ ID NO: 1 in the reply filed on 9/08/05 is acknowledged. The traversal is on the ground(s) that Claim 1 should be considered a linking claim and that several groups should be rejoined upon allowance of the generic claim. Applicant cites MPEP 809.03. Also, the restriction is traversed on the grounds that it would not be a burden to examine. This is not found persuasive because while applicant is correct in asserting that upon allowability of a generic linking claim the restriction requirement should be withdrawn if a generic claim becomes allowable. Claim 1, however, cannot be considered a linking claim because Claim 1 does not contain or encompass all the elements of the inventions of the other groups. For instance, Group III claims a pharmaceutical composition containing ADNF I, but also containing ADNF III, which is not part of the invention encompassed by claim 1. Applicant's argument that it would not be a burden has been considered and found not to be persuasive. The inventions art to unique products and methods requiring non-overlapping searches, and therefore would be a burden on the examiner.

Claim 7 is not directed to the elected species of SEQ ID NO: 1 and is therefore withdrawn. Claim 42, and 46-52 will be examined to the extent that they read on the currently elected invention and species. Claims 1-6, 8-9, and 42-53 are under consideration.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

2. The specification should be reviewed for improper recitation of hyperlinks. All such recitations should be deleted or amended such that the hyperlinks are rendered inactive. See MPEP § 608.01. See in particular, page 18, line 16 of the specification.

### ***Claim Objections***

3. Claims 42, and 49-52 are objected to because of the following informalities: Claims 42 and 49-53 contain subject matter directed to non-elected inventions. In particular the claims recite ADNF III in the method of reducing cell death. Appropriate correction is required.

4. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 5 recites the same sequence with no further limitations than claim 1.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-6, 8-9, 42-45, and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman (us patent 6174862, filed Oct. 17, 1994) in further view of Voet et al (1995) and Goodman (US patent number 4, 587, 046 issued in 1986).

Brenneman teaches the ADNF I fragment of SEQ ID NO: 1 (see Claim 1) and a method of reducing neuronal cell death by administering the polypeptide of SEQ ID NO: 1 (see claim 6 of Brenneman), which meets the limitations of claims 1 and claim 42. Brenneman teaches administration to spinal cord neurons, hippocampal neurons, cerebral cortical neurons and cholinergic neurons in claim 7, meeting the limitations of claim 53. Further, claim 1 recites the polypeptide of SEQ AID NO: 1 wherein the N- or C-terminus can be flanked by 1-40 amino acids, which meets the limitations of claim 8.

Brenneman does not teach the polypeptide of SEA ID NO: 1 or administration thereof wherein one or more, or all amino acids are D-amino acids instead of L-amino acids.

Voet et al (1995) teaches that the D-amino acids are more resistant to proteases than art their L-amino acid counterparts. Furthermore, Goodman teaches that incorporation of D-amino acids into peptides is particularly advantageous when those peptides are administered to patients, as the D-amino acids are resistant to proteolysis in vivo (see col 9, lines 48-54). Thus Voet and Goodman teach the value of having one or more D-amino acids incorporated into a protein to be administered to a patient, which meets the limitations of claims 1-6, 8-9, and 42-53.

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It would be obvious to one of ordinary skill in the art to make the product and perform the method of reducing neuronal death wherein one or more amino acids, or all amino acids are D-amino acids with a high expectation of success. The motivation to do so would be to increase the stability of the protein when administered to a patient.

### Conclusion

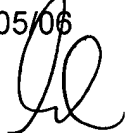
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.

3/05/06



JANET C. ANDRES  
SUPERVISORY PATENT EXAMINER